U.S. Department of Justice

United States Attorney
Eastern District of New York

ALB:CPK
F. #2016R01209

610 Federal Plaza
Central Islip, New York 11722

December 30, 2018

By ECF

Honorable Steven I. Locke
United States Magistrate Judge
United States Courthouse
820 Federal Plaza
Central Islip, New York 11722

Re: U.S. v. Lloyd Landsman, 17 CR 00653(SIL)

Dear Judge Locke:

The government writes in response to defendant Lloyd Landsman's ("Defendant LL") Sentencing Memorandum filed September 14, 2018 ("Sentencing Memo"). Defendant's sentencing is scheduled for November 9, 2018. This office concurs with the sentencing recommendation of the United States Probation Department ("Probation Recommendation") which seeks, inter alia, two years probation, a small fine, compliance with the Forfeiture Order and 200 hours of community service. This office agrees with the Probation Recommendation's characterization of Defendant LL's offense as "very serious" and that Defendant LL "blatantly disregarded directives by FDA-OCI agents to discontinue the use of these medications and to contact agents immediately." Probation Recommendation at 2.

This office also concurs with the Probation Recommendation's conclusion that defendant failed "to adequately acknowledge the level of potential danger his actions exposed his patients to." Id. For years, Defendant LL purchased drugs from a company, Pharmalogical Inc. whose principal was convicted of over 60 felony counts after a six week trial in this courthouse. After a reversal, the only defendant in that case who went to trial pled guilty earlier this year to felony misbranding and was sentenced recently by Judge Spatt to 32 months. Defendant LL was purchasing product for his patients from a company that was selling misbranded drugs. The evidence at trial showed that the company did not keep a tracing of the drug's origins and there was testimony that the drugs were not stored and transported properly. After all Defendant LL's purchases from this company which was engaged for years in illegal sales of misbranded and unapproved drugs, defendant was warned by the FDA agent not to purchase unapproved misbranded drugs anymore and

choose to keep on ordering the misbranded and unapproved drugs. There was no shortage of Botox in the marketplace and the only reason for defendant to ever purchase outside of the approved suppliers selling FDA approved drugs was to reduce his costs and thereby increase his profit.

Although the Sentencing Memo makes much of the knowledge requirements of the statute to which Defendant LL pled guilty, Defendant LL stated at his plea before this Court that "I knowingly and intentionally received from Canada and Great Britain and delivered to my patients for pay, a non-FDA approved injectable botox, botulinum toxin drug, Botox, that was misbranded because the label did not bear the symbol "RX only" and required black box warnings" and that Defendant LL knew that "the package was misbranded." Plea at 18-19. Of course, because of the public danger presented by conduct in this area, the statute is a strict liability crime. U.S. v. Dotterweich, 320 U.S. 277 (1943).

Defendant LL discusses at length in his Sentencing Memo an article and surmises that there is concern surrounding the prosecution of doctors who purchase "genuine Botox that is simply mislabeled." Sentencing Memo at 16. Such speculation is fully at odds with the FDA's critical mission involving maintaining the safety of prescription drugs. The FDA's ability to track and trace is impaired by such conduct, presenting a public danger. Defective drugs need to be traced to eliminate the supply of tainted drugs. Such tracing is impossible where physicians have circumvented the normal approved delivery system. In fact, defendant's argument trivializes the dangers to patients posed by the purchase of mislabeled drugs. In the many misbranding prosecutions brought by this office, it has been apparent that the storage and transport requirements are not adhered to by the companies engaged in the sale of unapproved misbranded drugs. In fact, testimony at the trial of the Pharmacological executive, who sold defendant some of these misbranded drugs, made this fully apparent. Nor is there any tracing possible which, as the testimony at that trial evidenced, makes a recall impossible further endangering future patients and the public at large. Thus, the danger to patients is twofold, the danger to the patient being treated of the dangers caused by the inadequate storage and transportation. Second, the danger to future patients and the public is presented by the inability to do a recall of drugs that do not have any traceable history. The Sentencing Memo's repeated assertions that it is only the packaging of the products that is different (Id. at 22) shows a complete lack of understanding of the dangers of misbranded drugs discussed above that are well known to this office from its numerous prosecutions involving misbranded drugs. Contrary to the Sentencing Memo's assertion, this office has not acknowledged that Dr. Landsman was a victim of Pharmacological. The doctors who purchased misbranded drugs from Pharamalogical spanned the range of victim to unindicted co-conspirator.

Regarding the Sentencing Memo's misleading characterizations of the plea discussions (Sentencing Memo at 22), the government will not dignify those comments by a new attorney uninvolved in the years of attempts to resolve this matter. There is no doubt from Defendant LL's statements at the plea that he knowingly purchased misbranded drugs. The only open question for this office was whether there was proof beyond a reasonable doubt that he did it to defraud his patients and/or the FDA.

As for the Sentencing Memo's false characterization of the FDA Special Agent's actions at Dr. Landsman's office, this office will not address and detail the false statements unless the Court believes that would be helpful in formulating a sentence.

Respectfully submitted,

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